

**REMARKS**

The amendments to claims 1, 15, 16, and 24 as well as the submission of a substitute specification (marked-up copy and clean copy), are respectfully submitted prior to initiation of the prosecution of this application in the U.S. Patent and Trademark Office.

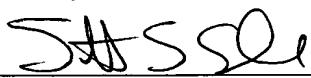
The above-noted amendments to the claims are respectfully submitted in order to more clearly and appropriately claim the subject matter which applicant considers to constitute his inventive contribution. No new matter is included in these amendments. In addition, the revisions to the Specification are submitted in order to clarify and correct the Specification and to conform it to all of the requirements of U.S. practice. No new matter is included in these amendments.

In view of the above, it is respectfully requested that these amendments now be entered, and that prosecution on the merits of this application now be initiated. If, however, for any reason the Examiner does not believe such action can be taken, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any objections which he may have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge applicant's Deposit Account No. 12-1095 therefor.

Dated: October 5, 2004

Respectfully submitted,

By 

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## DEVICE FOR SECURING SPINAL RODS

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The subject application is a divisional application of copending U.S. Appln. Serial No. 09/487,942 filed January 19, 2000, now USPN 6,565,565, which is a continuation-in-part of both U.S. Appln. Serial No. 09/167,439, filed October 6, 1998, now abandoned, and U.S. Appln. Serial No. 09/098,927, filed June 17, 1998, now USPN 6,090,111, the disclosures of which are herein incorporated by reference in their entireties.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

[0002] The subject disclosure relates to implantable spinal stabilization systems for surgical treatment of spinal disorders, and more particularly, to a device for connecting cylindrical spinal rods of a spinal stabilization system to the spine.

#### 2. Background of the Related Art

[0003] The spinal column is a complex system of bones and connective tissue which protects critical elements of the nervous system. Despite these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist through a wide range of motion. Trauma or developmental irregularities can result in spinal pathologies which limit this range of motion.

[0004] For many years, orthopedic surgeons have attempted to correct spinal irregularities and restore stability to traumatized areas of the spine through immobilization. Over the past ten years, spinal implant systems have been developed to

achieve immobilization. Examples of such systems are disclosed in U.S. Patent Nos. 5,102,412 and 5,181,917 to Rogozinski. Such systems often include spinal instrumentation having connective structures such as elongated rods which are placed on opposite sides of the portion of the spinal column intended to be immobilized. Screws and hooks are commonly utilized to facilitate segmental attachment of such connective structures to the posterior surfaces of the spinal laminae, through the pedicles, and into the vertebral bodies. These components provide the necessary stability both in tension and compression to achieve immobilization.

[0005] Various fastening mechanisms have been provided in the prior art to facilitate securement of screws and hooks to the connective structures of a spinal stabilization system. For example, U.S. Patent No. 5,257,993 to Asher discloses an apparatus for use in retaining a spinal hook on an elongated spinal rod. The apparatus includes a body extending upwardly from a hook portion and having an open ended recess for receiving a spinal rod and an end cap engageable with the body to close the recess. A set screw is disposed in the center of the end cap to clamp the rod in the recess of the body. The end cap and body are interconnectable by different types of connectors including a bayonet connector, a linear cam connector or a threaded connector. Other examples of fastening mechanism for facilitating attachment of screws and hooks to the connective structures of a spinal stabilization system are disclosed in U.S. Patent No. 5,437,669 to Yuan et al. and U.S. Patent No. 5,437,670 to Sherman et al.

[0006] In each of these prior art examples, threaded fasteners are used to facilitate securement of the connector to the

spinal rod. Yet it is well known that threaded fasteners can become loosened under the influence of cyclically applied loads commonly encountered by the spinal column. Furthermore, during assembly, excessive torque applied to a threaded fastener can cause damage to the fastener as well as to the connective device with which it is associated.

[0007] It would be beneficial to provide a more reliable and effective mechanism for facilitating the attachment of screws, hooks and clamps to the connective structures of a spinal stabilization system.

#### SUMMARY OF THE DISCLOSURE

[0008] The subject disclosure is directed to a device for securing a spinal rod to a fixation device such as a pedicle screw or a lamina hook. The device disclosed herein includes a head portion configured to receive a spinal rod, a locking cap configured to engage the head portion and the spinal rod upon rotation of the locking cap relative to the head portion to secure the position of the head portion relative to the spinal rod, and a fastener portion extending from the head portion and configured to engage the spine. The fastener portion of the device can be in the form of a screw, hook or clamp, or any other configuration known in the art.

[0009] The head portion of the device has a channel extending therethrough for receiving a spinal rod and the channel is preferably bounded by opposed side walls each having an arcuate engagement slot defined therein. The locking cap preferably has opposed arcuate engagement flanges configured for reception in the opposed arcuate engagement slots of the head portion upon rotation of the locking cap relative to the head portion. Preferably, the opposed engagement slots are each defined in

part by inclined slot surfaces, with the angle of the inclined surface of one engagement slot being opposite that of the opposed engagement slot. Similarly, the opposed engagement flanges are preferably each defined in part by inclined flange surfaces, with the angle of the inclined surface of one engagement flange being opposite that of the opposed engagement flange. The head portion also preferably includes structure for interacting with the locking cap to prevent the opposed side walls of the head portion from expanding radially outwardly when the arcuate flanges are engaged in the arcuate slots.

[0010] Preferably, the locking cap of the device is configured for rotation between an initial position in which the arcuate engagement flanges are 90° out of phase with the arcuate engagement slots, an intermediate position in which the arcuate engagement flanges are 45° out of phase with the arcuate engagement slots, and a locked position in which the arcuate engagement flanges are in phase and intimately engaged with the arcuate engagement slots.

[0011] In this regard, the bottom surface of the locking cap preferably includes a first recess oriented to accommodate a spinal rod when the locking cap is in an initial unlocked position, a second recesses which intersects the first recess at a first angle to accommodate a spinal rod when the locking cap is in an intermediate position, and a third recess which intersects the elongate recess at a second angle to accommodate a spinal rod when the locking cap is in a final locked position. In accordance with a preferred embodiment of the subject disclosure, the first recess is an elongate recess, the second recess is a transverse recess which intersects the elongate recess at a 45° angle, and the third recess is an

orthogonal recess which intersects the elongate recess at a 90° angle.

**[0012]** The subject disclosure is also directed to a device for securing a spinal rod to the spine which comprises a head portion having a channel extending therethrough configured to receive a spinal rod, a locking cap including a first portion configured to engage an interior surface of the head portion and a second portion configured to engage an exterior surface of a spinal rod received by the channel to secure the position of the head portion relative to the spinal rod, and a fastener portion depending from the head portion and configured to engage the spine.

**[0013]** Preferably, the locking cap is a two-piece structure which includes an upper portion configured to engage an interior surface of the head portion and a lower portion configured to engage an exterior surface of the spinal rod to secure the position of the head portion relative to the spinal rod upon rotation of the upper portion relative to the lower portion and the head portion. The upper portion of the locking cap includes a bottom surface having an axial reception bore defined therein and the lower portion of the locking cap includes an upper surface having an axial post extending therefrom configured to engage the axial reception bore in the bottom surface of the upper portion of the locking cap and facilitate the relative rotation of the two parts. The upper portion further includes opposed arcuate engagement flanges configured for cammed engagement in correspondingly configured opposed arcuate engagement slots formed in the opposed side walls of the head portion upon rotation of the upper portion relative to the lower portion. The lower portion further

includes a bottom surface having an elongated hemi-cylindrical recess that is oriented to accommodate a spinal rod extending through the channel in the head portion.

[0014] In accordance with one aspect of the subject disclosure, the fastener portion is formed monolithic with the head portion. In accordance with another aspect of the subject disclosure, the fastener portion is mounted for movement relative to the head portion. In this regard, the head portion defines a central axis oriented perpendicular to the spinal rod channel and the fastener portion is mounted for angular movement relative to the central axis of the head portion. More particularly, the fastener portion includes a generally spherical head and a threaded body which depends from the spherical head, and the head portion defines a seat to accommodate the spherical head and an aperture to accommodate the threaded body. In use, upon rotation of the upper portion of the locking cap relative to the lower portion of the locking cap into a locked position, the position of the head portion relative to the spinal rod and the position of the fastener relative to the head portion become fixed.

[0015] These and other unique features of the device disclosed herein and the method of installing the same will become more readily apparent from the following description of the drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0016] So that those having ordinary skill in the art to which the disclosed apparatus appertains will more readily understand how to construct and use the same, reference may be had to the drawings wherein:

[0017] Fig. 1 is a perspective view of an elongated spinal

rod of a spinal stabilization system having attached thereto a bone screw and a bone hook constructed in accordance with a first embodiment of the subject disclosure;

[0018] Fig. 2 is a perspective view of a locking cap which forms part of the bone screw and bone hook illustrated in Fig. 1, oriented in an inverted position for ease of illustration;

[0019] Fig. 3 is a perspective view of the bone screw and locking cap of Fig. 1 separated from one another for ease of illustration;

[0020] Fig. 4 is a cross-sectional view of the bone screw of the subject disclosure taken along line 4-4 of Fig. 1;

[0021] Fig. 5 is a cross-sectional view of the locking cap taken along line 5-5 of Fig. 3;

[0022] Figs. 6A through 6D illustrate operative steps associated with attaching the bone fastener of the subject disclosure to a spinal rod wherein:

[0023] Fig. 6A illustrates the step of positioning the spinal rod and locking cap in the reception channel of the head portion of a fastening device of the subject disclosure;

[0024] Fig. 6B illustrates the initial orientation of the locking cap relative to the head portion of a fastening device of the subject disclosure wherein the locking cap is in an unlocked position;

[0025] Fig. 6C illustrates the rotation of the locking cap relative to the head portion of a fastening device of the subject disclosure to a partially locked position; and

[0026] Fig. 6D illustrates the rotation of the locking cap relative to the head portion of a fastening device of the subject disclosure to a locked position;

[0027] Fig. 7 is a perspective view of a fastening device



constructed in accordance with a second embodiment of the subject disclosure;

**[0028]** Fig. 8 is a perspective view of the fastening device of Fig. 7 with the locking cap separated for ease of illustration;

**[0029]** Fig. 9 is a perspective view of the locking cap of the fastener device of Fig. 7, oriented in an inverted position for ease of illustration;

**[0030]** Fig. 10 is a cross-sectional view of the fastening device of Fig. 7 taken along line 10-10 of Fig. 7;

**[0031]** Fig. 11 is a perspective view of an elongated spinal rod of a spinal stabilization system having attached thereto another version of a bone screw and another version of a bone hook constructed in accordance with another embodiment of the subject disclosure;

**[0032]** Fig. 12A is an exploded perspective view of the bone screw of Fig. 11 with parts separated for ease of illustration including the two-piece locking cap and multi-axial fastener portion associated therewith;

**[0033]** Fig. 12B is a perspective view, looking upward from below, of the two-piece locking cap of the subject disclosure illustrating the bottom surface features of the component parts thereof;

**[0034]** Fig. 13 is a cross-sectional view of the bone screw of Fig. 11 taken along line 13-13 of Fig. 11 with the two-piece locking cap in a locked position;

**[0035]** Figs. 14A through 14C illustrate, in counter-clockwise progression, the operative steps associated with attaching the bone screw of Fig. 11 to a spinal rod by employing the two-piece locking cap of the subject disclosure,

wherein:

[0036] Fig. 14A illustrates the step of positioning the locking cap within the head portion of the bone screw;

[0037] Fig. 14B illustrates the initial unlocked orientation of the upper portion of the locking cap within the head portion of the bone screw; and

[0038] Fig. 14C illustrates the step of rotating the upper portion of the locking cap relative to the lower portion of the locking cap and the head portion of the bone screw into a locked position to secure the position of the bone screw with respect to the spinal rod;

[0039] Fig. 15 is an exploded perspective view of the bone hook of Fig. 11 with parts separated for ease of illustration including the two-piece locking cap associated therewith; and

[0040] Fig. 16 is a cross-sectional view of the bone hook of Fig. 11 taken along line 16-16 of Fig. 11 with the two-piece locking cap in a locked positions

[0041] These and other features of the apparatus disclosed herein will become more readily apparent to those having ordinary skill in the art from the following detailed description of the preferred embodiments taken in conjunction with the drawings.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0042] Referring now to the drawings wherein like reference numerals identify similar structural elements of the subject apparatus, there is illustrated in Fig. 1 a section of a spinal stabilization system constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 10.

[0043] Referring to Fig. 1, spinal stabilization system 10

includes an elongated spinal rod 12 having a circular cross-section and a substantially smooth outer surface finish. As illustrated, fastening devices in the form of a bone screw 14 and right-angle hook 16 are provided for securing spinal rod 12 to the spine during a spinal stabilization procedure. Both fastening devices employ a novel top-loaded locking cap, designated generally by reference numeral 20, which will be described in greater detail hereinbelow with reference to Fig. 2. The novel locking cap achieves significant clinical advantages over the prior art through its reliability and the ease in which it is installed during a spinal stabilization procedure.

**[0044]** It should be recognized that the subject disclosure is not limited in any way to the illustrated bone screw and right-angle hook. Rather, these particular fasteners are merely examples of the type of devices that can employ the novel locking cap disclosed herein. Other fasteners commonly utilized in spinal stabilization systems, such as, for example, hooks having alternative angular geometries as well as clamps are also envisioned. Indeed, it is envisioned that any component designed for attachment to an elongated spinal rod or transverse coupling rod, may incorporate the novel locking cap of the subject disclosure. Also, any number of fastening devices can be applied along the length of the spinal rod.

**[0045]** With continuing reference to Fig. 1, bone screw 14 includes a head portion 22 defining a horizontal axis and a vertical axis. A shank portion 24 depends from the head portion and a threaded portion 26 having a helical thread extending about the outer periphery depends from the shank portion. The helical thread is particularly adapted to securely engage the

vertebral bodies of the spine. A channel 28 extends through the head portion 22 along the horizontal axis thereof for receiving elongated spinal rod 12. As best seen in Fig. 3, channel 28 is defined by the interior surfaces of side walls 30 and 32 and the curved lower surface 29 which extends therebetween. Locking cap 20 is dimensioned and configured for reception and engagement in locking channel 28 to secure the position of bone screw 14 with respect to spinal rod 12 during a spinal stabilization procedure.

**[0046]** Referring again to Fig. 1, right-angle hook 16 includes a head portion 42 defining a horizontal axis and a vertical axis. A hook portion 46 depends from the head portion 42 for securement to a vertebral body of the spine. A channel 48 extends through the head portion 42 along the horizontal axis thereof for receiving elongated spinal rod 12. Channel 48 is defined by the interior surfaces of opposed side walls 50 and 52 and a curved lower surface extending therebetween. Locking cap 20 is dimensioned and configured for reception and engagement in channel 48 to secure the position of hook 16 with respect to spinal rod 12 during a spinal stabilization procedure.

**[0047]** Referring now to Fig. 2, there is illustrated locking cap 20 in an inverted position to best illustrate structural aspects thereof. Locking cap 20 includes a cylindrical head 62 and a flanged portion 64. The bottom surface 66 of flanged portion 64 includes an elongate recess 68 having a curvature complementary to spinal rod 12 for accommodating the spinal rod when locking cap 20 is in an unlocked position, shown for example in Fig. 6B. In such a position, the fastening device may be moved freely along or rotated about the longitudinal

axis of the spinal rod. Bottom surface 66 also includes a bifurcated orthogonal recess 70 which intersects the elongate recess at a 90° angle and has a curvature complementary to spinal rod 12 to accommodate the spinal rod when locking cap 20 is in a locked position, shown for example in Fig. 6D and Fig. 4. In addition, bottom surface 66 includes bifurcated first and second transverse recesses 72 and 74 which intersect the elongate recess 68 at opposite angles of intersection and have curvatures which are complementary to spinal rod 12 to accommodate the spinal rod when the locking cap 20 is in either of two intermediate positions, one of which is shown for example in Fig. 6C. In such a position, the fastening device retains the spinal rod but is not fully secured, and if desired by the surgeon, locking cap 20 can be rotated from the intermediate position and the fastener moved to an alternative location on the spinal rod. Preferably, the transverse recesses intersect the elongate recess at opposed 45° angles. However, those skilled in the art will readily appreciate that the transverse recess can be oriented at alternative intersecting angles. It is also contemplated that the bottom surface can be flat without any recesses.

**[0048]** Referring to Figs. 3 and 5, the cylindrical head 62 of locking cap 20 includes a hexagonal axial bore 80 extending partially therethrough for receiving a working implement such as a wrench to facilitate rotation of the locking cap 20 relative to the head portion 22 of the fastening device about the vertical axis defined thereby. It envisioned that alternative tooling configurations known in the art can also be utilized to facilitate axial rotation of locking cap 20 during a surgical procedure. Curved notches 76 and 78 are formed in

the inner surfaces of opposed walls 30 and 32 for accommodating the cylindrical head 62 of locking cap 20 when the locking cap is received and rotated within channel 28.

**[0049]** The flanged portion 64 of locking cap 20 is defined in part by two diametrically opposed arcuate engagement flanges 82 and 84 which are dimensioned and configured for operative engagement with two complementary diametrically opposed arcuate engagement slots 86 and 88 defined in the interior surfaces of the opposed side walls 30 and 32 of head portion 22. (See Fig. 4).

**[0050]** With continuing reference to Figs. 3 through 5, engagement flanges 82 and 84 define ramped camming surfaces 92 and 94, respectively. Camming surfaces 92 and 94 are of opposite angular inclination with respect to one another. More particularly, each engagement flange has a low side (e.g., 82a of flange 82) and a high side (e.g., 82b of flange 82), whereby the low sides of the two flanges are diametrically opposed from one another as are the high sides. Actually, the camming surfaces of the flanges are mirror images of one another. Thus, the locking cap can be initially oriented with either flange aligned to engage either slot. This versatility adds to the ease in which the locking cap is installed during a surgical procedure.

**[0051]** As best seen in Fig. 4, the arcuate engagement slots 86 and 88 in head portion 22 of fastener 14 have inclined surfaces which mate with the ramped camming surfaces 92 and 94 of flanges 82 and 84. As best seen in Fig. 5, the ramped camming surfaces 92 and 94 are tapered radially inwardly to enhance the interlock with the mating surfaces of arcuate engagement slots 86 and 88, which are also tapered to

complement the radially inward taper of camming surfaces 92 and 94. This interlocking relationship serves to prevent the opposed side walls 30 and 32 of head portion 22 from spreading radially outward as the arcuate flanges are engaged with the arcuate slots when the locking cap 20 is rotated to a locked position.

**[0052]** Figs 6A through 6D illustrate the steps in securing the fastening device to the spinal rod during a surgical procedure. Although attachment of a bone screw 14 is shown, it should be understood, as noted above, that other fastening devices, e.g., bone hooks, can be secured to the spinal rod 12 using the locking cap and head portion structure of the present disclosure. Initially, as illustrated in Fig. 6A, spinal rod 12 is moved into approximation with the horizontal channel 28 of head portion 22 such that the periphery of the spinal rod 12 is in registration with the curved surface 29 of the channel 28. Locking cap 20 is then top loaded into the channel along the vertical axis of the fastener in the direction of arrow a. At such a time, spinal rod 12 is accommodated within the elongate recess 68 defined in the bottom surface 66 of locking cap 20 and the bone screw 14 may be moved freely relative to the spinal rod. The opposed flanged sections 82 and 84 of locking cap 20 are 90° out of phase from the opposed arcuate engagement slots 86 and 88 defined in head portion 22, as shown for example in Fig. 6B.

**[0053]** Thereafter, as shown in Fig. 6C, locking cap 20 is rotated 45° relative to head portion 22 about the vertical axis thereof. At such a time, spinal rod 12 is accommodated within one of the two transverse recesses 72 or 74, depending upon the initial orientation of the locking cap 20 with respect to the

head portion. Thereupon, the opposed arcuate engagement flanges 82 and 84 of locking cap 20 are only partially engaged with the opposed arcuate engagement slots 86 and 88 defined in head portion 22, as they are 45° out of phase with the slots. Consequently, the locking cap holds the fastener 22 and spinal rod 12 together, but does not lock the fastener. In this position, the locking cap 20 can be readily rotated in the opposite direction to disengage from the spinal rod 12 to adjust the position of the bone screw 14 with respect to the spinal rod 12.

**[0054]** Once the desired position and orientation of the bone screw 14 has been attained, locking cap 20 is rotated another 90° to the locked position illustrated in Fig. 6D. At such a time, spinal rod 12 is accommodated within the orthogonal recess 70 defined in the bottom surface of locking cap 20. Thereupon, the opposed engagement flanges 82 and 84 of flanged portion 64 are fully engaged with the opposed engagement slots 86 and 88 of head portion 22 and the longitudinal and angular orientations of the bone screw 14 are fixed with respect to spinal rod 12, as illustrated in Fig. 4. It should be readily apparent that the manner and method by which bone screw 14 hook is attached to spinal rod 12 is identical to the manner and method by which hook 16 or other fasteners are attached to spinal rod 12.

**[0055]** Since the rotational range of locking cap 20 is limited, i.e., the locking cap can only be rotated 90°, it will be readily appreciated that the cap cannot be over-torqued. Thus, the damage often caused by over-tightening a conventional threaded locking mechanism, such as a set screw, is avoided. Furthermore, since the locking cap of the subject disclosure



has a predetermined locked position, it is unlikely that it will be under-torqued or left in a loose condition after installation as is common with threaded set screws found in the prior art. That is, by having a predetermined locked position, uniform locking forces are provided for all of the fastening devices used to secure the spinal rod 12 along its length and cross threading is reduced.

**[0056]** Referring now to Figs. 7 and 8, there is illustrated another fastening device constructed in accordance with a preferred embodiment of the subject disclosure and designated generally by reference numeral 110. Fastening device 110 is similar to fastening devices 12 and 14 in that it is particularly designed to facilitate securement of a spinal rod to the spine in a convenient manner. Fastening device 110 includes a head portion 122 having opposed side walls 130 and 132 which define a horizontal channel 128 in conjunction with the curved lower surface 129 extending therebetween. Arcuate tabs 176 and 178 project upwardly from side walls 130 and 132, respectively, for interacting with locking cap, 120.

**[0057]** Referring to Fig. 9, locking cap 120, which is shown in an inverted position for ease of illustration, includes a hexagonal head 162 a cylindrical body 163 and a flanged portion 164. The hexagonal head 162 is adapted and configured for interaction with a wrench or similar work implement. An annular channel 165 extends into the bottom surface of hexagonal head 162 for receiving arcuate tabs 176 and 168. This positive interaction serves to prevent the opposed side walls 130 and 132 of head portion 122 from spreading radially outwardly when arcuate flanges 182 and 184 of locking cap 120 are engaged in arcuate slots 186 and 188 of head portion 122 upon rotation of

locking cap 20 into a locked position. Thus, in this embodiment, the ramped camming surfaces 192 and 194 of the arcuate engagement flanges 182 and 184 need not be provided with radially inwardly directed tapers as provided on flanges 82 and 84 of the locking cap 20 of the embodiment of Figs. 1-6.

[0058] With continuing reference to Fig. 9, the bottom surface 166 of the flanged portion 164 of locking cap 120 is configured in substantially the same manner as the bottom surface 66 of locking cap 20 in that it is provided with an elongate recess 168 for accommodating a spinal rod when the locking cap 120 is in an unlocked position, first and second bifurcated transverse recesses 172 and 174 which intersect the elongate recess 168 at opposite 45° angles to accommodate the spinal rod when the locking cap 120 is in either of two intermediate positions, and a bifurcated orthogonal recess 170 which intersects the elongate recess at a 90° angle to accommodate the spinal rod when the locking cap 120 is in a final locked position, as shown in Fig. 10. It will be readily appreciated that locking cap 120 is engaged with fastening device 110 in a manner that is substantially similar to the manner in which locking cap 20 is engaged with bone fastener 14 and hook 16, and that the configuration of the bottom surface of flanged portion 164 provides the same benefits afforded by the flanged portion 64 of locking cap 20.

[0059] Referring now to Fig. 11, there is illustrated two additional fastening devices constructed in accordance with the subject disclosure in the form of a multi-axial bone screw 214 and a right-angle hook 216 which are provided for securing spinal rod 212 to the spine during a spinal stabilization procedure. Both fastening devices employ a novel top loaded

two-piece locking cap, designated generally by reference numeral 220, which will be described in greater detail hereinbelow with reference to Figs. 12 and 13. The novel two-piece locking cap achieves significant clinical advantages over the prior art through its reliability and the ease in which it is installed during a spinal stabilization procedure. As with respect to the previously described embodiments of Fig. 1, the novel two-piece locking cap may be used in conjunction with other types of fasteners commonly employed in spinal stabilization procedures. Moreover, while the two-piece locking cap illustrated in Fig. 11 is employed with a multi-axial bone screw, it is readily apparent that the same two-piece locking cap could be employed with a fixed axis bone screw such as that which is illustrated in Fig. 1.

**[0060]** Referring to Figs. 12A and 13, the multi-axial bone screw 214 includes a head portion 222 defining a horizontal axis "x" and a vertical axis "y". A channel 228 extends through the head portion 222 along the horizontal axis "x" for receiving an elongated spinal rod 212. Channel 228 is defined by the interior surfaces of the side walls 230 and 232 of head portion 222. Bone screw 214 further includes a fastener portion 224 which includes a generally spherical head 225 and a threaded body 226. Threaded body 226 depends from and is monolithically formed with the spherical head 225. The threaded body includes a helical thread formation that is particularly adapted to securely engage the vertebral bodies of the spine.

**[0061]** The head portion 222 of multi-axial bone screw 214 further defines a generally cylindrical vertical channel 227 which extends through and is aligned with the vertical axis "y" of the head portion 222. Vertical channel 227 is configured to

receive and accommodate the fastener portion 224 of bone screw 214. More particularly, as best seen in Fig. 13, a lower interior surface portion of vertical channel 227 defines an annular seating surface 229 configured to cooperate with the lower hemi-spherical region of spherical head 225. The cooperative engagement between the two structures permits the relative movement of the fastener portion 224 with respect to the head portion 222 about the vertical axis y. The multi-axial motion afforded thereto, enhances the operational range of bone screw 214, providing greater flexibility to the surgeon during a spinal stabilization procedure.

**[0062]** Bone screw 214 further includes an annular retention ring 232 that is accommodated within a corresponding annular groove 234 formed within the cylindrical wall of vertical channel 227 (see Fig. 13). Retention ring 232 is adapted to positively engage the spherical head 225 and aiding in its stabilization. In addition, as best seen in Fig. 13, the lower hemi-spherical region of head 225 is scored with a series of circular ridges adapted to enhance the frictional coefficient of the seating surface defined thereby.

**[0063]** Referring to Fig. 12A, bone screw 214 further includes a two-piece locking cap 220 which is dimensioned and configured for reception and engagement in the horizontal channel 228 of head portion 220 to secure the position of head portion 222 with respect to spinal rod 212 during a spinal stabilization procedure. In addition, as described in detail hereinbelow with respect to Fig. 13, the securement of locking cap 220 within channel 228 also achieves positive fixation of the angular position of the fastener portion 224 with respect to the head portion 222 and the vertical axis "y" defined

thereby.

**[0064]** As illustrated in Figs. 12A and 12B, locking cap 220 includes an upper portion 220a and a lower portion 220b. The upper portion 220a includes a cylindrical cap body 280 defining an axial reception port 282 for receiving a tool or working implement that applies torque to the cap during installation. Upper portion 220a further includes a pair of circumferentially opposed arcuate engagement flanges 284 and 286 which extend radially outwardly from cap body 280. Engagement flanges 284 and 286 include inclined radially inwardly slopping camming surfaces for cooperating with complementary opposed arcuate engagement slots 294 and 296 formed in the opposed side walls 230 and 232 of head portion 222 (see Fig. 13). As described in more detail hereinbelow with respect to Figs. 14a-14d, the flanges 284, 286 become engaged in corresponding slots 294, 296 upon rotation of the upper portion 220a of locking cap 220 relative to the head portion 222 of bone screw 214.

**[0065]** The lower portion 220b of locking cap 220 is configured for cooperative reception within the cylindrical vertical channel 227 of head portion 222 and is adapted to engage the spinal rod 212 extending through the horizontal channel 228 of head portion 222. More particularly, the body 285 of the lower portion 220b has curved exterior surfaces which complement the curvature of the walls defining vertical channel 227. Thus, when the locking cap 220 is loaded into vertical channel 227, a positive mating relationship is achieved between the lower portion 220b of locking cap 220 and vertical channel 227. As a result, the axial position of lower portion 220b becomes fixed with respect to head portion 222 and spinal rod 212. Furthermore, as best seen in Fig. 12B, a hemi-

cylindrical channel 299 is formed in the undersurface of lower portion 220b for intimately cooperating with the cylindrical spinal rod 212 upon loading the locking cap 220 in vertical channel 227. Body portion 285 includes an extension flange 302 which aides in the alignment and positioning of the lower cap portion 220a with respect to spinal rod 212.

[0066] As best seen in Fig. 12B, the bottom surface of the upper portion 220a of locking cap 220 includes a recessed seating area 287 and an associated axial reception bore 288. The recessed seating area 287 is dimensioned and configured to accommodate the body of the lower portion 220b of locking cap 220, while the reception bore 288 is dimensioned and configured to receive and engage an axial post 298 which projects from the upper surface 295 of the lower portion 220b of locking cap 220. More particularly, during assembly, when the axial post 298 is received by the reception bore 288, the top end of the post is swaged (flared out) to join the two components together (see Fig. 13). The interaction of the axial post 298 and axial reception bore 288 facilitates relative rotational movement of the upper portion 220a relative to the lower portion 220b when the locking cap 220 is loaded into and locked in the head portion 222 of bone screw 214 during a spinal stabilization procedure.

[0067] As described in detail hereinbelow with reference to Figs. 14A-14C, the two-part locking cap enables a surgeon to load the locking cap 220 into vertical channel 227 and properly position the lower portion 220b against the spinal rod 212 so as to ensure an intimate engagement between the hemicylindrical channel 299 and the cylindrical surface of the spinal rod. Thereafter, the upper portion 220a may be rotated

into a locked portion relative to the lower portion 220b.

**[0068]** Referring now in detail to Figs 14A-14C, during a spinal stabilization procedure, the fastener portion 226 of bone screw 214 is first seated within the head portion 222. Then, the head portion 222 is positioned at the surgical site in such a manner so that the elongated spinal rod 212 extends through the horizontal channel 228 as illustrated in Fig. 14A. Thereafter, if necessary, the fastener portion 226 may be moved into a desired angular orientation by the surgeon and subsequently mounted to the spinous process using suitable surgical instruments.

**[0069]** With reference to Fig. 14B, once the appropriate position of the fastener portion 226 has been established by the surgeon, the locking cap 220 is loaded into the vertical channel 227 of head portion 222 along the vertical axis "y" defined thereby. At such a time, the hemi-cylindrical channel 299 on the undersurface of lower portion 220b will become intimately engaged with the cylindrical surface of the spinal rod 212 and it will be maintained in a fixed axial orientation with respect to the spinal rod due to the mating relationship between the body of the lower portion 220b and the vertical channel 227.

**[0070]** Locking cap 220 must be loaded in such a manner so that the radially outwardly extending engagement flanges 284 and 286 of upper portion 220a are parallel to the axis of the spinal rod 212, as illustrated in Fig. 14B. Otherwise, the flanges will interfere with the opposed side walls 230 and 232 of the head portion 222. Furthermore, care must be taken to ensure that the upper portion 220a of locking cap 220 is positioned in such a manner so that the low sides of the

flanges (e.g. 284a) are aligned with the high sides of the engagement channels (e.g. 294a), or the flanges will not cammingly engage the channels upon rotation of the upper portion 220a of the locking cap 220 relative to the head portion 222 of bone screw 214.

**[0071]** Once the upper portion 220a of locking cap 220 has been properly oriented with respect to head portion 222 with the extension flange 302 in alignment with spinal rod 212, it is rotated in a clockwise direction about the vertical axis "y" relative to the lower portion 220b of locking cap 220 and the head portion 222 of bone screw 214 using an appropriate surgical implement or tool (not shown). Thereupon, the arcuate engagement flanges 284, 286 of upper portion 220 cammingly engage the corresponding engagement slots 284. Once rotated into a locked portion, the lower portion 220b of the locking cap 220 will be seated within the recessed seating area 287 defined in the bottom surface 285 of the upper portion 220a of locking cap 220 (See Fig. 13). At such a time, the position of the head portion 222 of bone screw 214 is fixed with respect to longitudinal axis of spinal rod 212 and the position of the fastener portion 226 of bone screw 214 is fixed with respect to the vertical axis "y" defined by head portion 222 of bone screw 214, as illustrated in Fig. 14C.

**[0072]** Referring now to Figs. 15 and 16, the right-angle hook 216 of the subject disclosure includes a head portion 242 defining a horizontal axis x and a vertical axis "y". A hook portion 246 depends from the head portion 242 to facilitate securement of the device to a vertebral body of the spine. A channel 248 extends through the head portion 242 along the horizontal axis thereof for receiving elongated spinal rod 212.



Channel 248 is defined by the interior surfaces of opposed upstanding side walls 250 and 252 and a contoured lower surface extending therebetween for complementing the shape of the rod. Channel 248 is further configured to receive a two-piece locking cap 220 adapted to secure the position of hook 216 with respect to spinal rod 212 during a spinal stabilization procedure.

**[0073]** As discussed hereinabove with respect to multi-axial bone screw 214, the locking cap 220 includes an upper portion 220a and a lower portion 220b which are rotatably joined together. The upper portion includes a pair of circumferentially opposed arcuate engagement flanges 284 and 286 for cooperating with complementary opposed arcuate engagement slots 255 and 257 formed in the opposed side walls 250 and 252 of head portion 242. As described in more hereinabove with respect-to Figs. 14A-14C, the flanges 284, 286 become engaged in corresponding slots 255, 257 upon rotation of the upper portion 220a of locking cap 220 relative to the lower portion 220b of the locking cap and the head portion 242 of right-angle hook 216.

**[0074]** Although the apparatus disclosed herein has been described with respect to preferred embodiments, it is apparent that modifications and changes can be made thereto without departing from the spirit and scope of the invention as defined by the claims.